



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Note to Reader
January 8, 1998

Background: As part of its effort to involve the public in the implementation of the Food Quality Protection Act of 1996 (FQPA), which is designed to ensure that the United States continues to have the safest and most abundant food supply. EPA is undertaking an effort to open public dockets on the organophosphate pesticides. These dockets will make available to all interested parties documents that were developed as part of the U.S. Environmental Protection Agency's process for making reregistration eligibility decisions and tolerance reassessments consistent with FQPA. The dockets include preliminary health assessments and, where available, ecological risk assessments conducted by EPA, rebuttals or corrections to the risk assessments submitted by chemical registrants, and the Agency's response to the registrants' submissions.

The analyses contained in this docket are preliminary in nature and represent the information available to EPA at the time they were prepared. Additional information may have been submitted to EPA which has not yet been incorporated into these analyses, and registrants or others may be developing relevant information. It's common and appropriate that new information and analyses will be used to revise and refine the evaluations contained in these dockets to make them more comprehensive and realistic. The Agency cautions against premature conclusions based on these preliminary assessments and against any use of information contained in these documents out of their full context. Throughout this process, If unacceptable risks are identified, EPA will act to reduce or eliminate the risks.

There is a 60 day comment period in which the public and all interested parties are invited to submit comments on the information in this docket. Comments should directly relate to this organophosphate and to the information and issues available in the information docket. Once the comment period closes, EPA will review all comments and revise the risk assessments, as necessary.

These preliminary risk assessments represent an early stage in the process by which EPA is evaluating the regulatory requirements applicable to existing pesticides. Through this opportunity for notice and comment, the Agency hopes to advance the openness and scientific soundness underpinning its decisions. This process is designed to assure that America continues to enjoy the safest and most abundant food supply. Through implementation of EPA's tolerance reassessment program under the Food Quality Protection Act, the food supply will become even safer. Leading health experts recommend that all people eat a wide variety of foods, including at least five servings of fruits and vegetables a day.

Note: This sheet is provided to help the reader understand how refined and developed the pesticide file is as of the date prepared, what if any changes have occurred recently, and what new information, if any, is expected to be included in the analysis before decisions are made. **It is not meant to be a summary of all current information regarding the chemical.** Rather, the sheet provides some context to better understand the substantive material in the docket (RED chapters, registrant rebuttals, Agency responses to rebuttals, etc.) for this pesticide.

Further, in some cases, differences may be noted between the RED chapters and the Agency's comprehensive reports on the hazard identification information and safety factors for all organophosphates. In these cases, information in the comprehensive reports is the most current and will, barring the submission of more data that the Agency finds useful, be used in the risk assessments.

A handwritten signature in black ink, appearing to read 'J. Housenger', is written over the typed name and title.

Jack E. Housenger, Acting Director
Special Review and Reregistration Division

August 3, 1998

MEMORANDUM

SUBJECT: OCCUPATIONAL AND RESIDENTIAL EXPOSURE ASSESSMENT
AND RECOMMENDATIONS FOR THE REREGISTRATION
ELIGIBILITY DECISION DOCUMENT FOR OXYDEMETON-
METHYL. REVISED TO REFLECT NEW TOXICOLOGICAL
ENDPOINTS AND AGGREGATE DERMAL AND
INHALATION RISK.

FROM: Kelly O'Rourke, Biologist
Chemistry and Exposure Branch 1
Health Effects Division (7509C)

TO: Paula Deschamp, Biologist - Risk Assessor
Reregistration Branch 2
Health Effects Division (7509C)

THRU: Francis B. Suhre, Branch Senior Scientist
Chemistry and Exposure Branch 1
Health Effects Division (7509C)

DP Barcode: D247985

Pesticide Chemical Codes: 058702

EPA Reg. Nos.: 7946-10, 10163-219, 10163-220, and 64014-9

EPA MRID Nos.: 00158006, 00158208, 00158209, 00158210, 412017-01,
43821401

LUIS Report Date: 10/16/96 and 6/3/97

PHED: Version 1.1

OCCUPATIONAL AND RESIDENTIAL EXPOSURE CHAPTER

In this document, which is for use in EPA's development of the Oxydemeton-methyl (ODM) Reregistration Eligibility Decision Document (RED), EPA presents the results of its review of the potential human health effects of occupational and residential exposure to oxydemeton-methyl (ODM). Included is a discussion of the adequacy of the occupational and residential exposure data that have been submitted in support of the reregistration of oxydemeton-methyl.

BACKGROUND

Due to concerns about reproductive effects, ODM was placed in Special Review in 1987. Previously submitted data from mixer/loader/applicator (MRID #s 00158006 and 41201701), and postapplication re-entry (MRID #s 00158208, 00158209, 00158210) studies were found not to meet Subdivision U or K Guideline requirements, and thus to be inadequate to support reregistration (see Appendix A). As part of a 1994 settlement agreement with EPA, ODM registrant Gowan Co. was granted an extension to submit the required data. In exchange, Gowan agreed to labeling restrictions requiring closed mixing/loading systems for aerial and chemigation applications, and agreed to implement a plan to phase in the use of closed mixing/loading systems for other application methods.

This document is a revision of the October 21, 1997 assessment. The changes reflect new toxicological endpoints that were identified in the latest ODM Hazard Identification Committee Report, dated May 7, 1998.

Criteria for Conducting Exposure Assessments

An occupational and/or residential exposure assessment is required for an active ingredient if (1) certain toxicological criteria are triggered and (2) there is potential exposure to handlers (mixers, loaders, applicators, etc.) during use or to persons entering treated sites after application is complete. For ODM, the toxicological criteria are met by the identification of endpoints for estimating short-term and intermediate-term risk. Potential exposure can occur as a result of agricultural uses; non-occupational exposure in residential settings is not likely.

Summary of Use Patterns of Formulations

Occupational-use products and homeowner-use products

At this time products containing ODM are intended primarily for occupational use. No products containing ODM are intended primarily for residential use. ODM is classified as a Restricted Use Pesticide (RUP). None of the registered occupational uses are likely to involve applications at residential sites.

Oxydemeton-methyl (ODM), S-[2-(Ethylsufinyl)ethyl] 0,0-dimethylphosphorothioate, is an organophosphate insecticide-acaricide formulated as an emulsifiable concentrate (25 percent a.i.), and as a ready-to-use liquid for tree injections (50 percent a.i.). No ODM end-use products

are currently available in water soluble bags (WSBs). However, as a result of the settlement agreement with EPA, Gowan has been involved in investigating the technical feasibility of packaging ODM in this fashion. Therefore, as an engineering control, a mixer/loader scenario for WSBs is included in this assessment.

According to the Metasystox-R label, ODM is used to control aphids, mites, leafhoppers, thrips, corn rootworm beetles and lygus bugs (1995 label only) on the following crops:

- **Field Crops:** cotton, field corn, popcorn, peppermint, spearmint, and sugar beets;
- **Seed Field Crops:** alfalfa, clover, safflower, sorghum;
- **Non-Bearing Fruits:** apples, apricots, cherries, citrus, crab apples, grapes, nectarines, peaches, pears, plums, prunes, quinces;
- **Vegetables:** beans (lima), broccoli, brussels sprouts, cauliflower, cabbage, cucumber, eggplant, head lettuce, onions, peppers, pumpkin, snapbeans, squash, turnips;
- **Melons:** muskmelon, watermelon; and,
- **Nuts:** filberts, walnuts.

In addition to these agricultural crops, ODM is registered for application to Christmas tree plantations, seed orchard trees, ornamental flowering plants, woody shrubs, and various ornamental and shade trees.

According to BEAD, ODM can be applied aurally (fixed wing or helicopter), by airblast sprayers, by groundboom sprayers, by bark treatment (e.g., brush-on or tree injection) and by soil injection. The Metasystox-R label also identifies another type of application--chemigation. According to this label, ODM can be delivered through the following sprinkler types: center pivot, lateral move, side roll, overhead solid set and low pressure irrigation systems. The current Metasystox-R label states that closed systems for mixing and loading must be used for all aerial application and chemigation systems.

Summary of Toxicity Concerns Relating to Occupational Exposures

Acute Toxicology Categories

Guideline studies for acute toxicity indicate that the technical grade of ODM is classified as category I for acute oral and dermal toxicities, category III for primary eye irritation, and category IV for primary dermal irritation. The manufacturing product (50 percent a.i.) is classified as category II for acute inhalation toxicity. The technical grade and manufacturing product of ODM are not classified as skin sensitizers.

Other Endpoints of Concern

The ODM Hazard Identification Assessment Review Committee report, dated May 7, 1998, (which supercedes the previous Hazard ID Committee report, dated July 27, 1997) indicates that there are toxicological endpoints of concern for ODM. A summary of this information is presented in Table 1.

Table 1. Toxicological Endpoints of Concern for ODM

Exposure Routes	Exposure Duration	Dose (mg/kg/day)	Effect	Study	Uncertainty Factor	Comment
Dermal	Short-term	NOEL 5.0	Plasma, RBC, and Brain ChE inhibition	7-day dermal toxicity (rat)	100	Route-specific study; MOE based on UF for inter-species (10x) extrapolation and intra-species variability(10x)
Dermal	Intermediate-term	NOEL 0.3	Brain ChE inhibition	14-day dermal toxicity (rat)	100	Route-specific study; MOE based on UF for inter-species (10x) extrapolation and intra-species variability(10x)
Inhalation	Any time period	LOEL 17.02 ^a	Clinical signs (tremors)	Acute inhalation study (rat)	300	Route-specific study; MOE based on UF for inter-species (10x) extrapolation, intra-species variability(10x), and lack of NOEL (3x)

^a Inhalation dose in mg/L was converted to mg/kg/day using the following equation, after adjusting the LOEL of 0.177 mg/L to 0.0979 mg ai/L by multiplying by 0.553 to account for the percent active ingredient:

Dose (mg/kg/day) = (LOEL (0.0979 mg/L) * Respiration rate of a young adult Sprague Dawley rat (10.26 L/hr) * Study length (4 hr/day)) / Body weight of a young adult Sprague Dawley rat (0.236 kg)

Epidemiological Information

The following data bases have been consulted for the poisoning incident data on the active ingredient Oxydemeton Methyl (PC Code: 058702):

1. OPP Incident Data System (IDS) - reports of incidents from various sources, including registrants, other federal and state health and environmental agencies and individual consumers, submitted to OPP since 1992. Reports submitted to the Incident Data System represent anecdotal reports or allegations only, unless otherwise stated. Typically no conclusions can be drawn implicating the pesticide as

a cause of any of the reported health effects. Nevertheless, sometimes with enough cases and/or enough documentation risk mitigation measures may be suggested.

2. Poison Control Centers - as the result of Data-Call-Ins issued in 1993, OPP received Poison Control Center data covering the years 1985 through 1992 for 28 organophosphate and carbamate chemicals. Most of the national Poison Control Centers (PCCs) participate in a national data collection system, the Toxic Exposure Surveillance System which obtains data from about 70 centers at hospitals and universities. PCCs provide telephone consultation for individuals and health care providers on suspected poisonings, involving drugs, household products, pesticides, etc.
3. California Department of Food and Agriculture (replaced by the Department of Pesticide Regulation in 1991) - California has collected uniform data on suspected pesticide poisonings since 1982. Physicians are required, by statute, to report to their local health officer all occurrences of illness suspected of being related to exposure to pesticides. The majority of the incidents involve workers. Information on exposure (worker activity), type of illness (systemic, eye, skin, eye/skin and respiratory), likelihood of a causal relationship, and number of days off work and in the hospital are provided.
4. National Pesticide Telecommunications Network (NPTN) - NPTN is a toll-free information service supported by OPP. A ranking of the top 200 active ingredients for which telephone calls were received during calendar years 1984-1991, inclusive has been prepared. The total number of calls was tabulated for the categories human incidents, animal incidents, calls for information, and others.

Conclusions

1. There were a total of 634 oxydemeton methyl cases in the PCC data base. Of these, 34 cases (5.4 percent) were occupational exposure; 471 (74.3 percent) involved exposure among non-occupational adults (e.g., bystanders exposed to spray drift) and 129 (20.3 percent) involved exposure to children under age six.
2. In California, poisoning incidents involving oxydemeton methyl as the primary cause of poisoning are relatively infrequent (less than 1 per year). The ratios of poisonings per 1,000 applications for both handlers and field workers is only about 1/4 the median for selected insecticides in California.
3. Overall, oxydemeton methyl was not among the 10 highest rankings of the 28 pesticides on measures of hazard derived from California and Poison Control Center data. Most of the risk from this product is due to use by pesticide handlers including applicators and mixer/loaders.
4. Detailed descriptions of incidents reported to the California Pesticide Illness Surveillance Program from 1982 through 1993 were reviewed. There were a total

of 20 cases in which oxydemeton methyl was either used alone or in combination with other chemicals but was judged to be responsible for the health effects. The majority of the illnesses were of a systemic type. The majority of incidents occur among handlers who mix, load, and apply oxydemeton methyl in agricultural fields.

Handler Exposures & Assumptions

EPA has determined that there are potential exposures to mixers, loaders, applicators, or other handlers during usual use-patterns associated with oxydemeton-methyl. Based on the use patterns 13 major exposure scenarios were identified for oxydemeton-methyl:

- (1a) mixing/loading liquid formulations for aerial/chemigation application;
- (1b) mixing/loading liquid formulations for groundboom application;
- (1c) mixing/loading liquid formulations for airblast sprayer application;
- (1d) mixing/loading liquid formulations for high-pressure handwand application;
- (2a) mixing/loading water soluble bags (gel packs) for aerial application/chemigation irrigation;
- (2b) mixing/loading water soluble bags (gel packs) for groundboom application
- (2c) mixing/loading water soluble bags (gel packs) for airblast sprayer application;
- (2d) mixing/loading water soluble bags (gel packs) for high-pressure handwand application;
- (3) applying sprays with fixed-wing aircraft;
- (4) applying sprays with helicopter aircraft;
- (5) applying using a groundboom sprayer;
- (6) applying using an airblast sprayer;
- (7) applying using a high-pressure handwand;
- (8) applying concentrated or dilute liquid to tree bark using a paintbrush;
- (9) tree injection using a ready-to-use liquid;
- (10) mixing/loading/applying sprays using soil injection;
- (11) mixing/loading/applying sprays using a backpack sprayer;
- (12) mixing/loading/applying sprays using a low pressure handwand;
- (13) flagging during aerial application (sprays)

Scenarios 2a, 2b, 2c, and 2d (water soluble bags, gel packs) are not listed on the most current labels, and are included for mitigation purposes only.

In deriving exposure estimates, the following assumption were employed:

Unit exposures	=	From PHED Version 1.1.
Application rates	=	Maximum label rates for example crops.
Acres/day	=	Standard HED Occupational/Residential default values based on application method, and modified as needed for specific crop/application method combinations (e.g. 20 acre/day for airblast application to trees, rather than the standard 40 acre/day airblast value).

As mentioned previously, none of the chemical-specific handler studies which were submitted were found to be acceptable for reregistration purposes, and were therefore not used to estimate exposures. Baseline dermal and inhalation exposure assessments using PHED Version 1.1 surrogate data are presented in Table 2. Tables 3 and 4 present the corresponding risk assessments for the short-term and intermediate-term dermal exposures, respectively. Table 5 presents the corresponding risk assessment for the inhalation exposures. Because the uncertainty factors are dissimilar for the dermal and inhalation routes (i.e., 100 and 300, respectively), the MOEs were combined using the aggregate risk index (ARI) method. ARIs, which are ratios (of the MOE to the uncertainty factor) adjusted to a common denominator of 1, are calculated using the following formula:

$$ARI = 1 / \{ [1 / (Dermal\ MOE / Dermal\ UF)] + [1 / (Inhalation\ MOE / Inhalation\ UF)] \}$$

An ARI is compared to an uncertainty factor of 1. Table 6 presents the ARIs for both short-term and intermediate-term exposures. Table 7 summarizes the caveats and parameters specific to each exposure scenario and corresponding risk assessment.

Daily dermal exposure is calculated using the following formula:

$$\begin{aligned} \text{Daily Dermal Exposure (mg ai/day)} = \\ \text{Unit exposure (mg ai/lb ai)} \times \text{Use Rate (lb ai/A or lb ai/gal)} \times \text{Daily Amount} \\ \text{Treated (A/day or gal/day)}. \end{aligned}$$

These calculations of daily exposure to oxydemeton-methyl by handlers are used to estimate the daily dermal dose for those handlers.

Daily inhalation exposure is calculated using the following formula:

$$\begin{aligned} \text{Daily Inhalation Exposure (mg ai/day)} = \\ \text{Unit Exposure (}\mu\text{g ai/lb ai)} \times (1\text{mg}/1000\mu\text{g conversion)} \times \text{Use Rate (lb ai/A or lb} \\ \text{ai/gal)} \times \text{Daily Amount Treated (A/day or gal/day)} \end{aligned}$$

These calculations of daily exposure to oxydemeton-methyl by handlers are used to estimate the daily inhalation dose for those handlers.

Table 2. Dermal and Inhalation Exposure to Oxydemeton-Methyl (ODM)

Exposure Scenario (Scenario #)	Baseline Dermal Unit Exposure (mg/lb ai) ^a	Baseline Inhalation Unit Exposure (ug/lb ai) ^b	Maximum Application Rate (lb ai/acre) ^c	Daily Acres Treated ^d	Baseline Daily Dermal Exposure (mg/day) ^e	Baseline Daily Inhalation Exposure (mg/day) ^f
Mixer/Loader Exposure						
Mixing/Loading Liquid Formulations for Aerial/Chemigation Application (1a)	2.9	1.2	(safflower) ^l 1.0	350	1,000	0.42
			(cabbage) 0.75		760	0.32
			(walnuts) 0.375		380	0.16
Mixing/Loading Liquid Formulations for Groundboom Application (1b)			(safflower) ^l 1.0	80	230	0.096
			(cabbage) 0.75		170	0.072
			(walnuts) 0.375		87	0.036
Mixing/Loading Liquid Formulations for Airblast Sprayer (1c)			(tree crops) 1.125	20	65	0.027
			(grapes) 0.375	40	44	0.018
Mixing/Loading Liquid Formulations for High-Pressure Handwand (1d)			(tree crops) 1.125	20	65	0.027
Mixing/Loading Water Soluble Bags (Gel Packs) for Aerial/Chemigation Application (2a)	See Engineering Controls	See Engineering Controls	(cabbage) 0.75	350	See Engineering Controls	See Engineering Controls
			(walnuts) 0.375			
Mixing/Loading Water Soluble Bags (Gel Packs) for Groundboom Application (2b)			(cabbage) 0.75	80		
			(walnuts) 0.375			
Mixing/Loading Water Soluble Bags (Gel Packs) for Airblast Sprayer (2c)			(tree crops) 1.125	20		
			(grapes) 0.375	40		
Mixing/Loading Water Soluble Bags (Gel Packs) for High-Pressure Handwand (2d)	(tree crops) 1.125	20				
Applicator Exposure						
Applying Sprays with Fixed-wing Aircraft (3)	See Engineering Controls	See Engineering Controls	0.75	350	See Engineering Controls	See Engineering Controls
Applying Sprays with Helicopter Aircraft (4)	See Engineering Controls	See Engineering Controls	0.75	350	See Engineering Controls	See Engineering Controls
Applying Sprays with a Groundboom (5)	0.014	0.74	0.75	80	0.84	0.044
Applying Sprays Using an Airblast (6)	0.36	4.5	(tree crops) 1.125	20	8.1	0.10
			(grapes) 0.375	40	5.4	0.068

Table 2. Dermal and Inhalation Exposure to Oxydemeton-Methyl (ODM)

Exposure Scenario (Scenario #)	Baseline Dermal Unit Exposure (mg/lb ai) ^a	Baseline Inhalation Unit Exposure (ug/lb ai) ^b	Maximum Application Rate (lb ai/acre) ^c	Daily Acres Treated ^d	Baseline Daily Dermal Exposure (mg/day) ^e	Baseline Daily Inhalation Exposure (mg/day) ^f
Applying Using a High-Pressure Handwand (7)	1.8	79	1.125	20	41	1.8
Applying Liquid Concentrate as a Tree Bark Treatment Using a Paintbrush (8)	180	280	2 lb ai/gal ^g	10 gal ^h	3,600	5.7
				5 gal ^h	1,800	2.8
Tree Injection (Ready-to-Use Liquid) (9)	No Data	No Data	No Data	No Data	No Data	No Data
Mixer/Loader/Applicator Exposure						
Soil Injection (10)	No Data	No Data	No Data	No Data	No Data	No Data
Backpack Sprayer/Knapsack (11)	2.5	30	0.75 lb ai/gal	40 gal	75	0.90
Low Pressure Handwand (12)	100	30	0.75 lb ai/gal	40 gal	3,000	0.90
Flagger Exposure						
Flagging Aerial (Sprays) (13)	0.011	0.35	0.75	350	2.9	0.092

a Baseline dermal unit exposure represents long pants, long sleeve shirt, no gloves, open mixing/loading, and open cab tractor.

b Baseline inhalation exposure represents no respirator.

c Application rates come from values found in the LUIS report and on ODM labels (EPA Reg. No. 10163-220 dated 1/7/97; FL960006 dated 3/29/96; and EPA Reg. No. 64014-9 dated 12/94). For some scenarios, a range of application rates is used to represent different crops/sites.

d Daily acres treated values are from EPA HED estimates of acreage that could be treated or volume handled in a single day for each exposure scenario of concern.

e Daily Dermal Exposure (mg/day) = Unit Exposure (mg/lb ai) * Appl. rate (lb ai/A) * Acres Treated

f Daily Inhalation Exposure (mg/day) = Unit Exposure (ug/lb ai) * (1mg/1000 ug) conversion * Appl. Rate (lb ai/A) * Acres Treated

g Maximum application rate for paintbrush application applies to application of undiluted liquid.

h For paintbrush application of ODM to tree bark, a range of 5-10 gallons per day of undiluted liquid represents an estimate of the volume of liquid applied in a single day (From EPA HED estimates).

i Extreme value is for the application of ODM for treatment of lygus bugs on safflower at an application rate of 4 pints per acre. This application rate was taken from the old ODM label dated 9/18/95. This rate is not listed on the new ODM label dated 1/7/97.

Table 3. Short-term Dermal MOEs for ODM at Baseline and with Mitigation Measures

Exposure Scenario (Scenario #)	Baseline Daily Dermal Dose ^a (mg/kg/day)	Baseline Dermal MOEs ^b	Risk Mitigation Measures					
			Additional PPE ^c			Engineering Controls ^d		
			Unit Dermal Exposure (mg/lb ai)	Daily Dermal Dose ^e (mg/kg/day)	MOE ^b	Unit Dermal Exposure (mg/lb ai)	Daily Dermal Dose ^e (mg/kg/day)	MOE ^b
Mixer/Loader Exposure and Dose Levels								
Mixing/Loading Liquid Formulations for Aerial/Chemigation Application (1a)	(safflower) 15	0.34	0.017	0.085	59	0.0086	0.043	120
	(cabbage) 11	0.46		0.064	78		0.032	160
	(walnuts) 5.4	0.92		0.032	160		0.016 ^f	310 ^f
Mixing/Loading Liquid Formulations for Groundboom Application (1b)	(safflower) 3.3	1.5		0.019	260		0.0098 ^f	510 ^f
	(cabbage) 2.5	2.0		0.015	340		0.0074 ^f	680 ^f
	(walnuts) 1.2	4.0		0.0073	690		0.0037 ^f	1,400 ^f
Mixing/Loading Liquid Formulations for Airblast Sprayer (1c)	(tree crops) 0.93	5.4		0.0055	920		0.0028 ^f	1,800 ^f
	(grapes) 0.62	8.0		0.0036	1,400		0.0018 ^f	2,700 ^f
Mixing/Loading Liquid Formulations for High- Pressure Handwand (1d)	(tree crops) 0.93	5.4		0.0055	920		0.0028 ^f	1,800 ^f
Mixing/Loading Water Soluble Bags (Gel Packs) for Aerial/Chemigation Application (2a)	See Engineering Controls	See Engineering Controls	See Engineering Controls	See Engineering Controls	See Engineering Controls	0.021	0.079	63
							0.039	130
Mixing/Loading Water Soluble Bags (Gel Packs) for Groundboom Application (2b)							0.018	280
							0.0090	560
Mixing/Loading Water Soluble Bags (Gel Packs) for Airblast Sprayer (2c)							(tree crops) 0.0068	740
							(grapes) 0.0045	1,100
Mixing/Loading Water Soluble Bags (Gel Packs) for High-Pressure Handwand (2d)						0.0068	740	

Table 3. Short-term Dermal MOEs for Oxydemeton-Methyl (ODM) at Baseline and with Mitigation Measures (continued)

Exposure Scenario (Scenario #)	Baseline Daily Dermal Dose ^a (mg/kg/day)	Baseline Dermal MOEs ^b	Risk Mitigation Measures					
			Additional PPE ^c			Engineering Controls ^d		
			Unit Dermal Exposure (mg/lb ai)	Daily Dermal Dose ^e (mg/kg/day)	MOE ^b	Unit Dermal Exposure (mg/lb ai)	Daily Dermal Dose ^e (mg/kg/day)	MOE ^b
Applicator Exposure and Dose Levels								
Applying Sprays with Fixed-wing Aircraft (3)	See Eng. Controls	See Eng. Controls	See Eng. Controls	See Eng. Controls	See Eng. Controls	0.0050	0.019	270
Applying Sprays with Helicopter Aircraft (4)	See Eng. Controls	See Eng. Controls	See Eng. Controls	See Eng. Controls	See Eng. Controls	0.0019	0.0071	700
Applying Sprays with a Groundboom (5)	0.012	420	0.011 ^f	0.0094 ^f	530 ^f	0.005 ^f	0.0043 ^f	1,200 ^f
Applying Sprays Using an Airblast (6)	(tree crops) 0.12	43	0.22	0.071	71	0.019	0.0061	820
	(grapes) 0.077	65		0.047	110		0.0041 ^f	1,200 ^f
Applying Using a High-Pressure Handwand (7)	0.58	8.6	0.36	0.12	43	None	None	None
Applying Liquids as a Tree Bark Treatment Using a Paintbrush (8)	52	0.097	22	6.3	0.80	None	None	None
	26	0.19		3.1	1.6		None	None
Tree Injection (Ready-to-Use Liquid) (9)	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data
Mixer/Loader/Applicator Exposure and Dose Levels								
Soil Injection (10)	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data
Backpack Sprayer/Knapsack (11)	1.1	4.7	1.6	0.69	7.3	None	None	None
Low Pressure Handwand (12)	43	0.12	0.37	0.16	32			
Flagger Exposure and Dose Levels								
Flagging Aerial (Sprays) (13)	0.041	120	0.010 ^f	0.038 ^f	130 ^f	0.00022 ^f	0.00083 ^f	6,100 ^f

Table 3. Short-term Dermal MOEs for Oxydemeton-Methyl (ODM) at Baseline and with Mitigation Measures (continued)

- a Baseline Daily Dermal Dose (mg/kg/day) = Baseline Daily Dermal Exposure (mg/day)/Body weight (70 kg). Baseline dermal exposures are reported in Table 2.
- b Dermal MOE values calculated using the following equation: $MOE = NOEL \text{ (mg/kg/day)} / \text{Dermal Dose (mg/kg/day)}$, where dermal NOEL = 5.0 mg/kg/day and an MOE of 100 is required.
- c Additional PPE:
- 1a, 1b, 1c, and 1d: Double layer of clothing (Protection Factor = 50% for the second layer) and chemical resistant gloves
 - 5: Double layer of clothing (Protection Factor = 50% for the second layer) and chemical resistant gloves
 - 6: Double layer of clothing (Protection Factor = 50% for the second layer) and chemical resistant gloves
 - 7: Double layer of clothing (Protection Factor = 50% for the second layer) and chemical resistant gloves
 - 8: Double layer of clothing (Protection Factor = 50% for the second layer) and chemical resistant gloves
 - 11: Double layer of clothing (Protection Factor = 50% for the second layer) and chemical resistant gloves
 - 12: Double layer of clothing (Protection Factor = 50% for the second layer) and chemical resistant gloves
 - 13: Double layer of clothing (Protection Factor = 50% for the second layer)
- d Engineering Controls:
- 1a, 1b, 1c, and 1d: Closed mixing, single layer of clothing, chemical resistant gloves
 - 2a, 2b, 2c, and 2d: Water soluble bags (gel packs), single layer of clothing no gloves
 - 3: Enclosed cockpit, single layer of clothing, no gloves
 - 4: Enclosed cockpit, single layer of clothing, no gloves
 - 5: Enclosed cab, single layer clothes, no gloves
 - 6: Enclosed cab, single layer clothes, chemical resistant gloves
 - 13: Enclosed truck (Protection Factor = 98%) single layer clothes, no gloves
- e Daily Dermal Dose (mg/kg/day) = [(Unit Dermal Exposure (mg/lb ai) * Max. App. Rate (lb ai/A) * Max. Treated)/Body Weight (70 kg)]
- f Although Baseline and/or Additional PPE MOE exceeds 100, MOEs were calculated for Additional PPE and/or Engineering Controls to be used in calculating the ARIs in Table 6.

Table 4. Intermediate-term Dermal MOEs for Oxydemeton-Methyl (ODM) at Baseline and with Mitigation Measures

Exposure Scenario (Scenario #)	Baseline Daily Dermal Dose ^a (mg/kg/day)	Baseline Dermal MOEs ^b	Risk Mitigation Measures					
			Additional PPE ^c			Engineering Controls ^d		
			Unit Dermal Exposure (mg/lb ai)	Daily Dermal Dose ^e (mg/kg/day)	MOE ^b	Unit Dermal Exposure (mg/lb ai)	Daily Dermal Dose ^e (mg/kg/day)	MOE ^b
Mixer/Loader Exposure and Dose Levels								
Mixing/Loading Liquid Formulations for Aerial/Chemigation Application (1a)	(safflower) 15	0.021	0.017	0.085	3.5	0.0086	0.043	7.0
	(cabbage) 11	0.028		0.064	4.7		0.032	9.3
	(walnuts) 5.4	0.055		0.032	9.4		0.016	19
Mixing/Loading Liquid Formulations for Groundboom Application (1b)	(safflower) 3.3	0.091		0.019	15		0.0098	31
	(cabbage) 2.5	0.12		0.015	21		0.0074	41
	(walnuts) 1.2	0.24		0.0073	41		0.0037	81
Mixing/Loading Liquid Formulations for Airblast Sprayer (1c)	(tree crops) 0.93	0.32		0.0055	55		0.0028	110
	(grapes) 0.62	0.48		0.0036	82		0.0018	160
Mixing/Loading Liquid Formulations for High- Pressure Handwand (1d)	(tree crops) 0.93	0.32		0.0055	55		0.0028	110
Mixing/Loading Water Soluble Bags (Gel Packs) for Aerial/Chemigation Application (2a)	See Engineering Controls	See Engineering Controls	See Engineering Controls	See Engineering Controls	See Engineering Controls	0.021	0.079	3.8
							0.039	7.6
Mixing/Loading Water Soluble Bags (Gel Packs) for Groundboom Application (2b)							0.018	17
							0.0090	33
Mixing/Loading Water Soluble Bags (Gel Packs) for Airblast Sprayer (2c)							0.0068	44
							0.0045	67
Mixing/Loading Water Soluble Bags (Gel Packs) for High-Pressure Handwand (2d)							0.0068	44

Table 4. Intermediate-term Dermal MOEs for Oxydemeton-Methyl (ODM) at Baseline and with Mitigation Measures (continued)

Exposure Scenario (Scenario #)	Baseline Daily Dermal Dose ^a (mg/kg/day)	Baseline Dermal MOEs ^b	Risk Mitigation Measures					
			Additional PPE ^c			Engineering Controls ^d		
			Unit Dermal Exposure (mg/lb ai)	Daily Dermal Dose ^e (mg/kg/day)	MOE ^b	Unit Dermal Exposure (mg/lb ai)	Daily Dermal Dose ^e (mg/kg/day)	MOE ^b
Applicator Exposure and Dose Levels								
Applying Sprays with Fixed-wing Aircraft (3)	See Engineering Controls		See Engineering. Controls			0.0050	0.019	16
Applying Sprays with Helicopter Aircraft (4)	No Data	No Data	No Data	No Data	No Data	0.0019	0.0071	42
Applying Sprays with a Groundboom (5)	0.012	25	0.011	0.0094	32	0.0050	0.0043	70
Applying Sprays Using an Airblast (6)	(tree crops) 0.12	2.6	0.22	0.071	4.2	0.019	0.0061	49
	(grapes) 0.077	3.9		0.047	6.4		0.0041	74
Applying Using a High-Pressure Handwand (7)	0.58	0.52	0.36	0.12	2.6	None	None	None
Mixing/Loading/Applying Liquids as a Tree Bark Treatment Using a Paintbrush (8)	52	0.0058	22	6.3	0.048	None	None	None
	26	0.012		3.1	0.095		None	None
Tree Injection (Ready-to-Use Liquid) (9)	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data
Mixer/Loader/Applicator Exposure and Dose Levels								
Soil Injection (10)	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data
Backpack Sprayer/Knapsack (11)	1.1	0.28	1.6	0.69	0.44	None	None	None
Low Pressure Handwand (12)	43	0.0070	0.37	0.16	1.9	None	None	None
Flagger Exposure and Dose Levels								
Flagging Aerial (Sprays) (13)	0.041	7.3	0.010	0.038	8.0	0.00022	0.00083	360

Table 4. Intermediate-term Dermal MOEs for Oxydemeton-Methyl (ODM) at Baseline and with Mitigation Measures (continued)

- a Baseline Daily Dermal Dose (mg/kg/day) = Baseline Daily Dermal Dose (mg/kg/day) from Table 3.
- b Dermal MOE values calculated using the following equation: $MOE = NOEL \text{ (mg/kg/day)} / \text{Dermal Dose (mg/kg/day)}$, where intermediate-term NOEL = 0.3 mg/kg/day and an MOE of 100 is required
- c Additional PPE:
 - 1a, 1b, 1c, 1d, 5, 6, 7, 8, 11, and 12: double layer clothing (Protection Factor = 50% for the second layer) with chemical resistant gloves
 - 13: double layer clothing (Protection Factor = 50% for the second layer)
- d Engineering Controls:
 - 1a, 1b, 1c, and 1d: closed mixing system, single layer of clothing and chemical resistant gloves
 - 2a, 2b, 2c, and 2d: water soluble bags (gel packs), single layer clothing, chemical resistant gloves
 - 3, 4: enclosed cockpit, single layer clothing, and no gloves
 - 5: enclosed cab, single layer clothing, and no gloves
 - 6: enclosed cab, single layer clothing and chemical resistant gloves
 - 13: enclosed truck (Protection Factor = 98%), single layer clothing, no gloves
- e $\text{Daily Dermal Dose (mg/kg/day)} = [(\text{Unit Dermal Exposure (mg/lb ai)} * \text{Max. App. Rate (lb ai/A)} * \text{Max. Treated}) / \text{Body Weight (70 kg)}]$

Table 5. Inhalation MOEs for Oxydemeton-Methyl (ODM) at Baseline and with Mitigation Measures

Exposure Scenario (Scenario #)	Baseline Daily Inhalation Dose ^a (mg/kg/day)	Baseline Inhalation MOEs ^b					
			Additional PPE ^c		Engineering Controls ^d		
			Daily Inhalation Dose D/M respirator ^e (mg/kg/day)	MOE ^b D/M respirator	Unit Inhalation Exposure (μg/lb ai)	Daily Inhalation Dose ^e (mg/kg/day)	MOE ^b
Mixer/Loader Exposures and Concentrations							
Mixing/Loading Liquid Formulations for Aerial/Chemigation Application (1a)	(safflower) 0.0060	2,800	NA	NA	0.083 ^h	(safflower) 0.00042 ^h	41,000 ^h
	(cabbage) 0.0045	3,800				(cabbage) 0.00031 ^h	55,000 ^h
	(walnuts) 0.0023	7,600				(walnuts) 0.00016 ^h	110,000 ^h
Mixing/Loading Liquid Formulations for Groundboom Application (1b)	(safflower) 0.0014	12,000				(safflower) 0.000090 ^h	180,000 ^h
	(cabbage) 0.0010	17,000				(cabbage) 0.000070 ^h	240,000 ^h
	(walnuts) 0.00051	33,000				(walnuts) 0.000040 ^h	480,000 ^h
Mixing/Loading Liquid Formulations for Airblast Sprayer (1c)	(tree crops) 0.00039	44,000				(tree crops) 0.000030 ^h	640,000 ^h
	(grapes) 0.00026	66,000				(grapes) 0.000020 ^h	960,000 ^h
Mixing/Loading Liquid Formulations for High- Pressure Handwand (1d)	(tree crops) 0.00039	44,000				(tree crops) 0.000030 ^h	640,000 ^h
Mixing/Loading Water Soluble Bags (Gel Packs) for Aerial/Chemigation Application (2a)	See Engineering Controls		See Engineering Controls	0.24	(cabbage) 0.00090	19,000	
					(walnuts) 0.00045	38,000	

Table 5. Inhalation MOEs for Oxydemeton-Methyl (ODM) at Baseline and with Mitigation Measures (continued)

Exposure Scenario (Scenario #)	Baseline Daily Inhalation Dose ^a (mg/kg/day)	Baseline Inhalation MOEs ^b					
			Additional PPE ^c		Engineering Controls ^d		
			Daily Inhalation Dose D/M respirator ^e (mg/kg/day)	MOE ^b D/M respirator	Unit Inhalation Exposure (μg/lb ai)	Daily Inhalation Dose ^g (mg/kg/day)	MOE ^b
Mixing/Loading Water Soluble Bags (Gel Packs) for Groundboom Application (2b)	See Engineering Controls		See Engineering Controls		0.24	(cabbage) 0.0021	83,000
						(walnuts) 0.00010	170,000
Mixing/Loading Water Soluble Bags (Gel Packs) for Airblast Sprayer (2c)	See Engineering Controls	See Engineering Controls		(tree crops) 0.000080		220,000	
				(grapes) 0.000050		330,000	
Mixing/Loading Water Soluble Bags (Gel Packs) for High-Pressure Handwand (2d)	See Engineering Controls	See Engineering Controls	See Engineering Controls			(tree crops) 0.000080	220,000
Applicator Exposures and Concentrations							
Applying Sprays with Fixed-wing Aircraft (3)	See Engineering Controls		See Engineering Controls		0.068	2.6E-4	67,000
Applying Sprays with Helicopter Aircraft (4)					0.0018	6.8E-6	2,500,000
Applying Sprays with a Groundboom (5)	0.00063	27,000	NA	NA	0.043 ^h	0.000040 ^h	460,000 ^h
Applying Sprays Using an Airblast (6)	(tree crops) 0.0014	12,000	NA	NA	0.45 ^h	0.00014 ^h	120,000 ^h
	(grapes) 0.00096	18,000	NA	NA		0.00010 ^h	180,000 ^h
Applying Using a High-Pressure Handwand (7)	0.025	670	NA	NA	None	None	None
Applying Liquids As a Tree Bark Treatment Using a Paintbrush (8)	0.081 (10 gal)	210	0.016	1,000	None	None	None
	0.040 (5 gal)	430	NA	NA			
Tree Injection (Ready-to-Use Liquid) (9)	No Data	No Data	No Data	No Data	No Data	No Data	No Data

Table 5. Inhalation MOEs for Oxydemeton-Methyl (ODM) at Baseline and with Mitigation Measures (continued)

Exposure Scenario (Scenario #)	Baseline Daily Inhalation Dose ^a (mg/kg/day)	Baseline Inhalation MOEs ^b					
			Additional PPE ^c		Engineering Controls ^d		
			Daily Inhalation Dose D/M respirator ^e (mg/kg/day)	MOE ^b D/M respirator	Unit Inhalation Exposure (<i>μ</i> g/lb ai)	Daily Inhalation Dose ^e (mg/kg/day)	MOE ^b
Mixer/Loader/Applicator Exposure and Dose Levels							
Soil Injection (10)	No Data	No Data	No Data	No Data	No Data	No Data	No Data
Backpack Sprayer (11)	0.013	1,300	NA	NA	None	None	None
Low Pressure Handwand (12)	0.013	1,300	NA	NA	None	None	None
Flagger Exposure and Dose Levels							
Flagging Aerial (Sprays) (13)	0.0013	13,000	NA	NA	0.007 ^h	0.000026 ^h	650,000 ^h

a Baseline Daily Inhalation Dose (mg/kg/day) = Baseline Inhalation Exposure (mg/day) / Body Weight (70 kg). Baseline inhalation exposures are reported in Table 2.

b MOE = NOEL (mg/kg/day) / Baseline Daily Inhalation Dose (mg/kg/day), where NOEL = 17.02 mg/kg/day. An MOE of 300 is required.

c Additional PPE: Use of dust mist (D/M) respirator was necessary for the paintbrush scenario. The vapor pressure of ODM is 2.85 E-05 Torr at 20°C.

d Engineering Controls:

1a, 1b, 1c, and 1d: Closed mixing/loading system

2a, 2b, 2c, and 2d: Water soluble bags or gel packs

3, 4 : Enclosed cockpit

5, 6: Enclosed cab

13: Enclosed truck

e Daily Inhalation Dose values for dust mist respirator represent a 5 fold protection factor

f Daily Inhalation Dose values for organic vapor removing respirator with a pesticide prefilter represent a 10 fold protection factor

g Daily Inhalation Dose for Engineering Controls = [(Eng. Cont. Unit Inhalation Exposure (μ g/lb ai) * (1 mg/1,000 μ g) conversion factor * Appl. Rate (lb ai/A) * Max Treated)/Body Weight (70 kg)].

h Although Baseline MOE exceeds 300, MOEs were calculated for Engineering Controls to be used in calculating the ARIs in Table 6.

Table 6. Short-term and Intermediate-term Aggregate Risk Indices for Baseline, Additional PPE, and Engineering Controls

Exposure Scenario (Scenario #)	Baseline					Additional PPE					Engineering Controls				
	Inhalation MOE ^a	Short-term		Intermediate-term		Inhalation MOE ^a	Short-term		Intermediate-term		Inhalation MOE ^c	Short-term		Intermediate-term	
		Dermal MOE ^b	ARI ^c	Dermal MOE ^d	ARI ^c		Dermal MOE ^b	ARI ^c	Dermal MOE ^d	ARI ^c		Dermal MOE ^b	ARI ^c	Dermal MOE ^d	ARI ^c
Mixer/Loader Exposure and Dose Levels															
Mixing/Loading Liquid Formulations for Aerial/Chemigation Application (1a)	2,800	0.34	0.0034	0.021	0.00021	2,800	59	0.55	3.5	0.035	41,000	120	1.2	7.0	0.07
	3,800	0.46	0.0046	0.028	0.00028	3,800	78	0.73	4.7	0.047	55,000	160	1.6	9.3	0.093
	7,600	0.92	0.0092	0.055	0.00055	7,600	160	1.5	9.4	0.094	110,000	310	3.1	19	0.19
Mixing/Loading Liquid Formulations for Groundboom Application (1b)	12,000	1.5	0.015	0.091	0.00091	12,000	260	2.4	15	0.15	180,000	510	5.1	31	0.31
	17,000	2.0	0.02	0.12	0.0012	17,000	340	3.2	21	0.21	240,000	680	6.7	41	0.41
	33,000	4.0	0.04	0.24	0.0024	33,000	690	6.5	41	0.41	480,000	1,400	14	81	0.81
Mixing/Loading Liquid Formulations for Airblast Sprayer (1c)	44,000	5.4	0.054	0.32	0.0032	44,000	920	8.7	55	0.55	640,000	1,800	18	110	1.1
	66,000	8.0	0.080	0.48	0.0048	66,000	1,400	13	82	0.82	960,000	2,700	27	160	1.6
Mixing/Loading Liquid Formulations for High-Pressure Handwand (1d)	44,000	5.4	0.054	0.32	0.0032	44,000	920	8.7	55	0.55	640,000	1,800	18	110	1.1
Mixing/Loading Water Soluble Bags (Gel Packs) for Aerial/Chemigation Application (2a)	See Engineering Controls			See Engineering Controls		See Engineering Controls			See Engineering Controls		19,000	63	0.62	3.8	0.038
											38,000	130	1.3	7.6	0.076
Mixing/Loading Water Soluble Bags (Gel Packs) for Groundboom Application (2b)											83,000	280	2.8	17	0.17
											170,000	560	5.5	33	0.33
Mixing/Loading Water Soluble Bags (Gel Packs) for Airblast Sprayer (2c)											220,000	740	7.3	44	0.44
											330,000	1,100	11	67	0.67
Mixing/Loading Water Soluble Bags (Gel Packs) for High-Pressure Handwand (2d)											220,000	740	7.3	44	0.44
Applicator Exposure and Dose Levels															
Applying Sprays with Fixed-wing Aircraft (3)	See Engineering Controls			See Engineering Controls		See Engineering Controls			See Engineering Controls		67,000	270	2.7	16	0.16
Applying Sprays with Helicopter Aircraft (4)	See Engineering Controls			See Engineering Controls		See Engineering Controls			See Engineering Controls		2,500,000	700	7.0	42	0.42

Table 6. Short-term and Intermediate-term Aggregate Risk Indices for Baseline, Additional PPE, and Engineering Controls (continued)

Exposure Scenario (Scenario #)	Baseline					Additional PPE					Engineering Controls				
	Inhalation MOE ^a	Short-term		Intermediate-term		Inhalation MOE ^a	Short-term		Intermediate-term		Inhalation MOE ^c	Short-term		Intermediate-term	
		Dermal MOE ^b	ARI ^c	Dermal MOE ^d	ARI ^c		Dermal MOE ^b	ARI ^c	Dermal MOE ^d	ARI ^c		Dermal MOE ^b	ARI ^c	Dermal MOE ^d	ARI ^c
Applying Sprays with a Groundboom (5)	27,000	420	4.0	25	0.25	27,000	530	5.0	32	0.32	460,000	1,200	12	70	0.70
Applying Sprays Using an Airblast (6)	12,000	43	0.43	2.6	0.026	12,000	71	0.7	4.2	0.042	120,000	820	8.0	49	0.49
	18,000	65	0.64	3.9	0.039	18,000	110	1.1	6.4	0.064	180,000	1,200	12	74	0.74
Applying Using a High-Pressure Handwand (7)	670	8.6	0.083	0.52	0.0052	670	43	0.36	2.6	0.026	Not Feasible			Not Feasible	
Mixing/Loading/Applying Liquids as a Tree Bark Treatment Using a Paintbrush (8)	210	0.097	0.00097	0.0058	0.000058	210	0.80	0.0079	0.048	0.00048	Not Feasible			Not Feasible	
	430	0.19	0.0019	0.012	0.00012	430	1.6	0.016	0.095	0.00095	Not Feasible			Not Feasible	
Tree Injection (Ready-to-Use Liquid) (9)	No Data			No Data		No Data			No Data		No Data			No Data	
Mixer/Loader/Applicator Exposure and Dose Levels															
Soil Injection (10)	No Data			No Data		No Data			No Data		No Data			No Data	
Backpack Sprayer/Knapsack (11)	1,300	4.7	0.046	0.28	0.0028	1,300	73	0.072	0.44	0.0044	Not Feasible			Not Feasible	
Low Pressure Handwand (12)	1,300	0.12	0.0012	0.007	0.000070	1,300	32	0.3	1.9	0.019	Not Feasible			Not Feasible	
Flagger Exposure and Dose Levels															
Flagging Aerial (Sprays) (13)	13,000	120	1.2	7.3	0.073	13,000	130	1.3	8.0	0.08	650,000	6,100	59	360	3.6

Note: An ARI greater than 1 is considered acceptable.

- a Baseline Inhalation MOEs from Table 5. Baseline inhalation MOEs were used to calculate both Baseline and Additional PPE ARIs because they were considered acceptable (i.e., greater than 300) without the addition of respirator protection factors.
- b Short-term Dermal MOEs for Baseline, Additional PPE, and Engineering Controls from Table 3. Baseline dermal unit exposure represents long pants, long sleeve shirt, no gloves, open mixing/loading, and open cab tractor.

Table 6. Short-term and Intermediate-term Aggregate Risk Indices for Baseline, Additional PPE, and Engineering Controls (continued)

	Additional PPE:
	1a, 1b, 1c, 1d, 5,
	6, 7, 8, 11, and 12: double layer clothing (Protection Factor = 50% for the second layer) with chemical resistant gloves
	13: double layer clothing (Protection Factor = 50% for the second layer)
	Engineering Controls:
	1a, 1b, 1c, and 1d: closed mixing system, single layer of clothing and chemical resistant gloves
	2a, 2b, 2c, and 2d: water soluble bags (gel packs), single layer clothing, chemical resistant gloves
	3, 4: enclosed cockpit, single layer clothing, and no gloves
	5: enclosed cab, single layer clothing, and no gloves
	6: enclosed cab, single layer clothing and chemical resistant gloves
	13: enclosed truck (Protection Factor = 98%), single layer clothing, no gloves
c	Aggregate Risk Index = $1/\{[1/(\text{Dermal MOE}/\text{Dermal UF})] + [1/(\text{Inhalation MOE}/\text{Inhalation UF})]\}$ where an ARI greater than 1 is considered acceptable.
d	Intermediate-term Dermal MOEs for Baseline, Additional PPE, and Engineering Controls from Table 4. Clothing scenarios are the same as those for short-term dermal MOE.
e	Inhalation MOEs for Engineering Controls from Table 5.

Additional PPE:
8: dust mist (D/M) respirator; the vapor pressure of ODM is 2.85 E-05 Torr at 20°C.

Engineering Controls:
1a, 1b, 1c, and 1d: Closed mixing/loading system
2a, 2b, 2c, and 2d: Water soluble bags or gel packs
3, 4 : Enclosed cockpit
5, 6: Enclosed cab
13: Enclosed truck

Table 7. Exposure Scenario Descriptions for Uses of Oxydemeton-Methyl (ODM)

Exposure Scenario (Number)	Data Source	Standard Assumptions ^a (8-hr work day)	Comments ^b
Mixer/Loader Exposure			
Mixing Liquid Formulations (1a, 1b, 1c, and 1d)	PHED V1.1	350 acres for aerial and chemigation, 80 acres groundboom, and 40 acres airblast.	<p>Baseline: Hands, dermal, and inhalation = AB grades. Dermal = 72 to 122 replicates; hands = 53 replicates; inhalation = 85 replicates. High confidence in all data. No protection factor was needed to define the unit exposure.</p> <p>PPE: The same dermal data are used as for the baseline, and chemical resistant glove data are used for hands. Hand data are AB grades with 59 replicates. High confidence in hand data.</p> <p>Engineering Controls: Hands, dermal, and inhalation = AB grades; Dermal = 16 to 22 replicates; hands = 31 replicates (w. gloves); inhalation = 27 replicates. High confidence in hands, dermal, and inhalation data. Gloves are worn during the use of engineering controls.</p> <p>PHED data were used for baseline, no protection factors (PFs) were necessary. A 50% PF was added to simulate coveralls for PPE. Engineering Controls data were monitored with chemical resistant gloves.</p>
Mixing/Loading Water Soluble Bags (Gel Packs) (2a, 2b, 2c, and 2d)	PHED V1.1	350 acres for aerial and chemigation, 80 acres for groundboom, and 40 acres airblast.	<p>Engineering Controls (water soluble packets, specifically gel packs): Hands and dermal = AB grade. Dermal = 6 to 15 replicates and hands = 5 replicates. Inhalation = all grades. Inhalation = 15 replicates. Low confidence in all data</p> <p>PHED data based on wettable powder in water soluble bags.</p>
Applicator Exposure			
Fixed-wing Aircraft Application of Liquid Formulations (3)	PHED V1.1	350 acres	<p>Engineering controls: Dermal and inhalation = A,B,C, grades; Hands = AB grades. Dermal = 24 to 48 replicates; hands = 34 replicates; inhalation = 23 replicates. Medium confidence in all data.</p> <p>PHED data were used for engineering controls data, no PFs were necessary.</p>
Helicopter Application of Liquid Formulations (4)	PHED V1.1	350 acres	<p>Engineering Controls: Hands and inhalation = A grade and dermal = C grade. Hands = 1 replicates; dermal = 3 replicates; and inhalation = 3 replicates. Low confidence in dermal, hands, and inhalation data.</p> <p>PHED data were used for engineering controls data, no PFs were necessary.</p>

Table 7. Exposure Scenario Descriptions for Uses of Oxydemeton-Methyl (ODM) (continued)

Exposure Scenario (Number)	Data Source	Standard Assumptions ^a (8-hr work day)	Comments ^b
Groundboom Application (5)	PHED V1.1	80 acres	<p>Baseline: Hands, dermal, and inhalation = AB grades. Dermal = 23 to 42 replicates; hands = 29 replicates; inhalation = 22 replicates. High confidence in all data.</p> <p>PPE: The same dermal data are used as for baseline. Hands = ABC grades and 21 replicates. Medium confidence in hand data.</p> <p>Engineering Controls: Dermal and hands = ABC grades, Dermal = 20 to 31 replicates; hands = 16 replicates. Medium confidence in hands data. Inhalation = AB grade, with 16 replicates and high confidence level.</p> <p>PHED data were used for baseline, no PFs were necessary. A 50% PF was added to the PPE scenario only to simulate coveralls.</p>
Applying Liquids with an Airblast Sprayer (6)	PHED V1.1	40 acres	<p>Baseline: Hands, dermal, and inhalation = AB grades. Dermal = 32 to 49 replicates; hands = 22 replicates; inhalation = 47 replicates. High confidence in all data.</p> <p>PPE: The same dermal data are used as for the baseline. Hands = AB grade with 18 replicates and high confidence level. Dermal = AB grades with 31 to 48 replicates and high confidence.</p> <p>Engineering Controls: Hands and dermal = AB grades. Dermal = 20 to 30 replicates; hands = 20 replicates. High confidence in dermal data. Inhalation = 9 replicates. Low confidence in inhalation data. No glove data back calculated from glove data assuming a 90% protection factor for gloves.</p> <p>No PFs were used for baseline data. A 50 percent PF was used for PPE to simulate coveralls.</p>
Applying Using a High-Pressure Handwand (7)	PHED V1.1	20 acres	<p>Baseline: Dermal and inhalation = All grades. Hands = C grades. Dermal = 9-11 replicates; hands = 2 replicates; inhalation = 11 replicates. Low confidence in dermal, hand, and inhalation data. Hands data back calculated from glove data using a 90% PF.</p> <p>PPE: The same dermal data are used as for baseline.</p>
Applying Liquids as a Tree Bark Treatment Using a Paintbrush (8)	PHED V1.1	10 gallons and 5 gallons	<p>Baseline and PPE: Dermal and inhalation = C grade; hands = B grade. Dermal = 14 to 15 replicates; hands = 15 replicates; inhalation = 15 replicates. Low confidence in dermal data. Medium confidence in inhalation data. A 5-fold PF (e.g., 80% PF) was applied to the baseline inhalation data.</p> <p>PHED data was used for baseline data. A 50 percent PF was added to PPE to simulate coveralls and a 90 percent PF was to simulate gloves.</p>
Tree Injection (Ready -to-Use Liquid) (9)	No Data	No Data	No Data

Table 7. Exposure Scenario Descriptions for Uses of Oxydemeton-Methyl (ODM) (continued)

Exposure Scenario (Number)	Data Source	Standard Assumptions ^a (8-hr work day)	Comments ^b
Mixer/Loader/Applicator Exposure			
Soil Injection (10)	No Data	No Data	No Data
Backpack Sprayer (11)	PHED V1.1	40 gal. occupational	<p>Baseline: Hand data are C grade, dermal are AB grades, and inhalation data are A grades. Hand = 11 replicates (back calculated from glove data assuming a 90% protection factor for gloves); dermal = 9 to 11 replicates; and inhalation = 11 replicates. Low confidence in hand/dermal and inhalation data.</p> <p>PPE: The same dermal data are used as for the baseline.</p> <p>Engineering Controls: Not feasible for this scenario.</p>
Low Pressure Handwand (12)	PHED V1.1	40 gal. occupational	<p>Baseline: Dermal and inhalation = ABC grades, hands = All grades. Low confidence in hands/dermal data. Medium confidence in inhalation data. Hands = 70 replicates, dermal = 9 to 80 replicates, and inhalation = 80 replicates.</p> <p>PPE: Hands = ABC grades with 10 replicates. Low confidence in dermal/hand data. The same dermal data are used as for the baseline coupled with a 50% protection factor to account for an additional layer of clothing.</p> <p>Engineering Controls: Not feasible.</p>
Flagger Exposure			
Flagger (13)	PHED V1.1	350 acres	<p>Baseline: Hands, dermal, and inhalation AB grades. Dermal = 18 to 28 replicates; hands = 30 replicates; and inhalation = 28 replicates. High confidence in dermal, hands, and inhalation data.</p> <p>PPE: The same dermal data are used as for the baseline. Hand data are AB grades with 30 replicates and low confidence.</p> <p>Engineering Controls: Enclosed truck (98% protection factor) data are used as surrogate for engineering controls for flaggers. Dermal, hands, and inhalation = AB grades. Dermal = 18 to 28 replicates; hands = 30 replicates; and inhalation = 28 replicates. High confidence in dermal, hand, and inhalation data.</p>

^a Standard Assumptions based on an 8-hour work day as estimated by HED. BEAD data were not available.

^b Data grades are defined by EPA SOP for meeting Subdivision U Guidelines. Acceptable grades are matrices with grades A and B data. Data confidence are assigned as follows:

High= grades A and B and 15 or more replicates

Medium = grades A, B, and C and 15 or more replicates; Low = grades A, B, C, D, and E or any combination of grades with less than 15 replicates

Postapplication Exposure and Assumptions

EPA has determined that there is potential exposure to persons entering treated sites after application is complete. Postapplication exposures may occur to agricultural workers following applications to the crops identified in the use summary during routine crop-production tasks, such as scouting, hoeing, thinning, and harvesting activities. Current labels include a restricted-entry interval (REI) of 48 hours, or 72 hours for regions where average rainfall is less than 25 inches per year.

Four reentry studies (one on grapes, two on cauliflower and broccoli, and one covering cauliflower, cotton, bell peppers, and sugar beets) were conducted for ODM formulated as Metasystox-R. No data are available for the other crops listed in the use summary. The EPA reviews of three of the studies concluded that they do not meet the requirements of Subdivision K. Nonetheless, the results are reported below for each study as a range finder. MOE calculations employed the intermediate-term endpoint (0.3 mg/kg/day) rather than the short-term because most workers re-entering treated sites to perform typical crop production activities where ODM is used are expected to have more than seven days of exposure.

Study 1. Degradation of Dislodgeable Metasystox-R Residue on Grape Foliage, San Joaquin County, California 1984 (MRID No. 00158210).

Metasystox-R was applied to grape foliage in Northern San Joaquin County, CA, at a rate of 0.9 lb ai/300 gallons/acre. Dislodgeable foliar residue (DFR) samples were collected at 10 sampling intervals using the Gunther & Iwata method. Duplicate DFR sample sets of 40 leaf discs (2.54 cm in diameter) were collected. Concurrent dermal and inhalation samples were not measured. The Dermal Dose and MOE of grape harvesters are estimated in Table 8 using a surrogate transfer coefficient (T_c) of 10,000 cm²/hour.

Table 8. Postapplication Dose and MOE to Grape Harvesters

Sampling Interval (DAT) ^a	Mean DFR ($\mu\text{g}/\text{cm}^2$) ^b	Dermal Dose ($\text{mg}/\text{kg}/\text{day}$) ^c	MOE ^d
Pre-Application	ND	ND	Not applicable
1-hour	0.921	1.1	0.3
24-hour	0.442	0.51	0.6
48-hour	0.525	0.60	0.5
72-hour	0.450	0.51	0.6
4	0.152	0.17	1.8
5	0.356	0.41	0.7
7	0.233	0.27	1.1
10	0.168	0.19	1.6
14	0.034	0.039	7.7

ND=nondetected

^a Days after treatment (DAT) unless otherwise specified.

^b Mean DFR of duplicate samples. DFR values represent ODM parent and its sulfone analogue oxidation product.

^c Dermal Dose ($\text{mg}/\text{kg}/\text{day}$) = $[\text{DFR } (\mu\text{g}/\text{cm}^2)] \times [10,000 \text{ T}_c (\text{cm}^2/\text{hr})] \times [1 \text{ mg}/1,000 \mu\text{g} \text{ conversion}] \times [8 \text{ hr}/\text{day}] / 70 \text{ kg [Body Weight]}$

^d MOE = NOEL (0.3 $\text{mg}/\text{kg}/\text{day}$) / Dermal Dose ($\text{mg}/\text{kg}/\text{day}$); MOE of 100 is considered adequately protective.

Study 2. *Degradation of Oxydemeton-Methyl (Metasystox-R) Residues on Cauliflower and Broccoli Foliage: Salinas Valley, California 1984 (MRID No. 00158208).*

Metasystox- R was applied to cauliflower (6 fields) and broccoli (1 field) using groundboom sprayers at a rate of 0.5 lb ai/acre (60 to 80 gallons of water per acre) in the Salinas Valley, CA, in July and August 1984. DFR samples were collected at the 7 fields (mature cauliflower, very young cauliflower, and broccoli) using the Gunter & Iwata method. Triplicate DFR sample sets of 16 leaf discs (2.54 cm in diameter) were collected. Concurrent dermal and inhalation samples were not measured. The dermal dose and MOE of harvesters are estimated in Table 9 using a surrogate T_c of 1,000 cm²/hour.

Table 9. Postapplication Dose and MOE to Cauliflower/Broccoli Harvesters

Sampling Interval	Mean DFR ($\mu\text{g}/\text{cm}^2$)		Dermal Dose (mg/kg/day) ^c		MOE ^d	
	Cauliflower ^a	Broccoli ^b	Cauliflower	Broccoli	Cauliflower	Broccoli
Pre-appl	ND	ND	ND	ND	NA	NA
~1-hr	0.130	0.215	0.015	0.025	20	12
6-hr	0.092	NS	0.011	NS	29	NS
12-hr	0.076	0.117	0.0087	0.013	35	22
30-hr	0.061	NS	0.0070	NS	43	NS
33-hr	NS	0.112	NS	0.013	NS	23
36-hr	0.054	NS	0.0062	NS	49	NS
40-hr	NS	0.120	NS	0.014	NS	22
54-hr	0.050	NS	0.0057	NS	53	NS
58-hr	NS	0.087	NS	0.0099	NS	30
60-hr	0.054	NS	0.0062	NS	49	NS
78-hr	0.037	NS	0.0042	NS	71	NS
7 days	0.032	NS	0.0037	NS	82	NS

NS=not sampled, ND=nondetected

^a Includes mature cauliflower (fields 1 - 5) mean only; excludes the very young plants (field 6)

^b Broccoli was only sampled in field 7.

^c Dermal Dose (mg/kg/day)=[DFR ($\mu\text{g}/\text{cm}^2$)]*[1,000 T_c (cm²/hr)]*[1 mg/1,000 μg conversion]*[8 hr/day]/70 kg [Body Weight]

^d MOE = NOEL (0.3 mg/kg/day)/Dermal Dose (mg/kg/day); MOE of 100 is necessary.

Study 3. *Degradation of Dislodgeable Metasystox-R Residue on Cauliflower and Broccoli Foliage in Santa Barbara and San Luis Obispo Counties, California (MRID No. 00158209).*

Metasystox- R was applied to cauliflower (5 fields) and broccoli (2 fields) at a rate of 0.5 lb ai/acre (50 to 60 gallons of water per acre) in CA (1984). DFR samples were collected at the 7 fields using the Gunter & Iwata method. Triplicate DFR sample sets of 15 leaf discs (2.5 cm in diameter) were collected. Concurrent dermal and inhalation samples were not measured. Dermal Dose and MOE of harvesters are estimated in Table 10 using a surrogate T_c of 1,000 cm^2/hour .

Table 10. Postapplication Dose and MOE to Cauliflower/Broccoli Harvesters

Sampling Interval	Mean DFR ($\mu\text{g}/\text{cm}^2$) ^a		Dermal Dose ($\text{mg}/\text{kg}/\text{day}$) ^b		MOE ^g	
	Cauliflower	Broccoli	Cauliflower	Broccoli	Cauliflower	Broccoli
Pre-appl	ND	ND ^c	ND	ND ^c	NA	NA
1- to 4-hr	0.129	0.146	0.015	0.017	20	18
24-hr	0.063	0.104	0.0072	0.012	42	25
48-hr	0.072	0.086	0.0082	0.0098	37	31
72-hr	0.054	0.064	0.0062	0.0074	48	41
96-hr	0.032 ^d	NS	0.0036	NS	83	NA
~7 days	0.015 ^e	0.014	0.0017	0.0016	180	190
~14 days	0.004 ^f	ND	0.00046	ND	650	NA

NS=not sampled NA = Not applicable

ND=nondetected

Note: Each field was irrigated during the study period.

^a Mean DFR of triplicate samples at 5 cauliflower and 2 broccoli fields

^b Dermal Dose ($\text{mg}/\text{kg}/\text{day}$)=[DFR ($\mu\text{g}/\text{cm}^2$)]*[1,000 T_c (cm^2/hr)]*[1 $\text{mg}/1,000 \mu\text{g}$ conversion]*[8 hr/day]/70 kg [Body Weight]

^c In 1 of the 2 fields the preapplication sample was ND, the other field had a preapplication sample of 0.01 $\mu\text{g}/\text{cm}^2$.

^d Only 2 of the 5 fields were sampled.

^e Only 4 of the 5 fields were sampled.

^f Seven of the 15 samples were ND (the detection limit was used for the ND samples).

^g MOE = NOEL (0.3 $\text{mg}/\text{kg}/\text{day}$)/Dermal Dose ($\text{mg}/\text{kg}/\text{day}$); MOE of 100 is necessary.

Study 4. *Oxydemeton Methyl - Dislodgeable Residues on various Crops* (MRID No. 43821401)

This study examines foliar and soil Dislodgeable residue data collected following spray application of ODM. The crops evaluated include: cauliflower, cotton, bell peppers, and sugar beets. Leaf disk samples were collected from all four crops, and soil samples were collected from the cauliflower and sugar beet test sites. Soil samples were collected in duplicate. The leaf disk samples were collected in triplicate and are presented in Table 11 below. The absorbed dermal dose and MOE of harvesters are estimated in Table 11 using a surrogate T_c of 1,000 cm²/hour. MOEs were calculated on Dislodgeable residue data collected following spray application of ODM.

Soil Data:

Soil residues from the cauliflower and sugar beet sites were also analyzed. The soil Dislodgeable residues from the cauliflower site ranged from a mean value of 4.515 ppm on day "0" and 5.685 ppm on day "1" to 2.860 ppm on day "7". The samples collected on day "35" had a value of 0.005 ppm. The soil Dislodgeable residues from the sugar beet site ranged from a mean value of 6.325 ppm on day "0" and 7.510 ppm on day "1" to 3.450 ppm on day "14" to 0.545 ppm on day "35". Analytical detection limit was not given for either site. These data are not used to calculate human risk because concurrent dermal exposure data were not monitored. No soil transfer coefficients are available at this time to relate soil residues to human exposure.

Table 11. Postapplication Dose and MOE for Cauliflower/Cotton/Bell Pepper/Sugar Beet Harvesters

Sampling Interval	Mean DFR ($\mu\text{g}/\text{cm}^2$)				Dermal Dose ($\text{mg}/\text{kg}/\text{day}$) ^a				MOE ^b			
	Cauliflower	Cotton	Bell Pepper	Sugar Beets	Cauliflower	Cotton	Bell Pepper	Sugar Beets	Cauliflower	Cotton	Bell Pepper	Sugar Beets
0	0.277	0.422	1.849	6.174	0.032	0.048	0.21	0.71	9.5	6.2	1.4	0.43
1	0.050	0.286	1.794	4.073	0.0057	0.033	0.21	0.47	53	9.2	1.5	0.64
2	0.048	0.217	0.88	2.224	0.0055	0.025	0.10	0.25	55	12	3.0	1.2
5	0.022	0.034	0.644	NS	0.0025	0.0039	0.074	NS	120	77	4.1	NS
7	0.013	0.024	0.546	1.521	0.0015	0.0027	0.062	0.17	200	110	4.8	1.7
14	ND	ND	0.305	2.56	--	--	0.035	0.29	--	--	8.6	1.0
21	ND	ND	0.157	1.645	--	--	0.018	0.19	--	--	17	1.6
28	ND	ND	0.069	0.560	--	--	0.0079	0.064	--	--	38	4.7
35	ND	ND	0.053	0.189	--	--	0.0061	0.022	--	--	50	14

NS = not sampled ND = nondetected

Note: The LOQ value for cauliflower is $0.009 \mu\text{g}/\text{cm}^2$; for cotton the LOQ is $0.013 \mu\text{g}/\text{cm}^2$; and for both bell pepper and sugar beets the LOQ value is $0.020 \mu\text{g}/\text{cm}^2$

^a Dermal Dose ($\text{mg}/\text{kg}/\text{day}$) = $[\text{DFR } (\mu\text{g}/\text{cm}^2) * [1,000 \text{ T}_c (\text{cm}^2/\text{hr})] * [1 \text{ mg}/1,000 \mu\text{g} \text{ conversion}] * [8 \text{ hr}/\text{day}]/70 [\text{Body Weight}]$

^b MOE = NOEL ($0.3 \text{ mg}/\text{kg}/\text{day}$)/Dermal Dose ($\text{mg}/\text{kg}/\text{day}$); MOE of 100 is necessary

(RISK)

Occupational and Residential

Short-term Dermal Exposures

Using an estimated average body weight of 70 kg for short-term exposure, daily dermal dose is calculated with the following formula:

$$\text{Daily Dermal Dose (mg ai/kg/day)} =$$

$$\text{Daily Dermal Exposure (mg ai/day)} \times 1/\text{body weight (kg)}$$

Calculations of daily dermal dose of oxydemeton are used to assess the dermal risk to those exposed to oxydemeton-methyl (ODM). The dermal MOEs were calculated using a NOEL of 5.0 mg/kg/day for short-term exposures in the following formula (percent absorption was not included in the calculation because the short-term endpoint was derived from a dermal study):

$$\text{Short-term Dermal MOE} = \text{NOEL (mg/kg/day)} / \text{Daily Dermal Dose (mg/kg/day)}$$

Short-term Dermal Risk From Handler Exposures

The calculations of short-term dermal risk indicate that the MOEs are more than **100** at **baseline** for the following scenarios:

- (5) Applying sprays with a groundboom (high confidence in hand dermal data; no PFs used), and
- (13) Flagging aerial sprays (high confidence in all data; no PFs used).

The calculations of short-term dermal risk indicate that the MOEs are more than **100** with additional **PPE** for the following scenarios:

- (1a) Mixing/loading liquid formulations for aerial/chemigation application using an application rate of 0.375 lb ai/acre (e.g., walnuts),
- (1b) Mixing/loading liquid formulations for groundboom application (all application rates),
- (1c) Mixing/loading liquid formulations for airblast sprayer application (all application rates),
- (1d) Mixing/loading liquid formulations for application with a high-pressure handwand, and
- (6) Applying sprays with an airblast using an application rate of 0.375 lb ai/acre (e.g., grapes).

The calculations of short-term dermal risk indicate that the MOEs are more than **100** with **engineering controls** for the following scenarios:

- (1a) Mixing/loading liquid formulations for aerial/chemigation application using an application rate of 1.0 lb ai/acre and 0.75 lb ai/acre (e.g., safflower and cabbage),
- (2b) Mixing/loading water soluble bags (gel packs) for groundboom application,
- (2c) Mixing/loading water soluble bags (gel packs) for airblast sprayer,
- (2d) Mixing, loading water soluble bags (gel packs) for high-pressure handwand,
- (3) Applying sprays with fixed-wing aircraft,
- (4) Applying sprays with helicopter, and
- (6) Applying sprays with an airblast using an application rate of 1.125 lb ai/acre (e.g., tree crops).

Intermediate-term Dermal

Using an estimated average body weight of 70 kg for intermediate-term exposure, daily dermal dose is calculated with the following formulae:

$$\text{Daily Dermal Dose (mg ai/kg/day)} =$$

$$\text{Daily Dermal Exposure (mg ai/day)} \times 1/\text{Body Weight (kg)}$$

Calculations of daily dermal dose of oxydemeton are used to assess the dermal risk to those exposed to oxydemeton-methyl (ODM). The dermal MOEs were calculated using a NOEL of 0.3 mg/kg/day for intermediate-term exposures in the following formula:

$$\text{Intermediate-term Dermal MOE} = \text{NOEL (mg/kg/day)} / \text{Daily Dermal Dose (mg/kg/day)}$$

Intermediate-term Dermal Risk From Handler Exposures

The calculations of intermediate-term dermal risk indicate that MOEs are more than **100** at **baseline** for none of the scenarios.

The calculations of intermediate-term dermal risk indicate that MOEs are more than **100** with **additional PPE** for none of the scenarios.

The calculations of intermediate-term dermal risk indicate that MOEs are more than **100** with **engineering controls** for the following scenarios:

- (1c) Mixing/loading liquid formulations for airblast spraying (all application rates),
- (1d) Mixing/loading liquid formulations for application with a high-pressure handwand, and
- (13) Flagging aerial sprays.

Discussion of Dermal Risk Estimates

Four general parameters enter into the calculations for handler dermal exposure: unit exposure value (derived from PHED V1.1); application rate (from product labels); area treated in a typical workday (estimates based on available usage information); and the worker's body weight

(taken from the draft Exposure Factors Handbook). The relative value of each of these parameters is described below:

- PHED values are approximately median exposures (i.e. central tendency point estimates) over the available data. That is, 50 percent of workers doing the same activity would be expected to have *higher* unit exposures, and 50 percent would be expected to have *lower* unit exposures. These values are derived from actual exposure studies where the same formulation types, equipment, and methods were employed as are used for ODM. Typically, there is high variability among replicates in exposure studies, often covering a range of orders of magnitude. EPA considers unit exposure values derived from PHED to be no higher than average.
- Application rates are the maximum labeled rates for the sites identified. Usually applications are made at varying rates depending on a number of factors including the degree of the pest problem and environmental considerations. Typically, actual application rates vary by a factor of 2 to 3 (recommended rates for ODM vary by up to a factor of two for a given crop). That is, if the maximum rate is 1 lb per acre, EPA expects that most applications will be made at rates ranging from around 1/3 or 1/2 lb per acre up to 1 lb per acre. “Typical” application rates are usually lower than the maximum rate for a given site, although use of the maximum rate is not considered rare. EPA considers the use of the maximum rate in estimation of exposure and risk to be a reasonable high-end assumption, given that often a pesticide is not efficacious at less than the maximum labeled rate, depending on the conditions under which it is applied.
- Area treated per day for the various application methods are standard values used by the former Occupational and Residential Exposure Branch. These were arrived at after much internal discussion, and are considered to represent typical to reasonable high-end acreages.
- Body weight is the standard 70 kg value for adults, which is routinely used by the Agency. This is identified in the Exposure Factors Handbook as the mean body weight for both sexes of adults in all age groups combined, rounded to one significant figure.

Of these four variables, the only one which can be considered to be “conservative” in the ODM calculations is application rate, which was estimated at maximum label rates for various crops and scenarios. However, for ODM, recommended application rates vary by up to only a factor of two on the label (e.g. from 1.5 to 3 pints/acre), while for some crops only a single rate is listed. Thus the dermal exposure estimates should be considered close to typical, rather than conservative or “high-end” bounding-type estimates. Back-calculations indicate that in order for the intermediate-term MOE to exceed 100 for airblast applicators in enclosed cabs and wearing chemical-resistant gloves, the number of acres treated would have to be no more than 9.8 at the maximum label rate, or 19.6 at one-half the maximum label rate.

The relatively high exposures for tree bark painting compared with other scenarios, such as airblast application, reflect the relatively high magnitude of the unit exposure (mg per lb ai handled) in PHED for this scenario. The PHED scenario for painting was based on a fungicide applied at an average rate of 0.0459 lb a.i. per replicate. Extrapolating the monitored scenario of

0.0459 lb a.i. to the ODM rate of 2.0 lb a.i. (max), the linear relationship assumed between exposure and lb a.i. handled may overestimate the risk.

Inhalation Exposures

Potential daily inhalation exposure is calculated using the following formula:

$$\text{Daily Inhalation Exposure (mg/day)} = \text{Unit Exposure } (\mu\text{g ai/lb ai}) * \\ \text{Conversion Factor (1 mg/1000}\mu\text{g)} * \text{Use Rate (lb ai/acre)} * \\ \text{Daily Acres Treated (acres/day)}$$

Potential daily inhalation dose is calculated using the following formula and assuming a body weight of 70 kg:

$$\text{Inhalation Dose (mg ai/kg/day)} = \text{Daily Inhalation Exposure (mg ai/day)} \\ * [1/\text{Body Weight (kg)}]$$

Inhalation MOEs are calculated using the following formula:

$$\text{Inhalation MOE} = \text{NOEL (mg/kg/day)} / \text{Daily Inhalation Dose (mg ai/kg/day)}$$

An inhalation NOEL was not available; therefore, a LOEL of 17.02 mg/kg/day was used. This value, in units of mg/kg/day, was converted from the adjusted LOEL of 0.0989 mg ai/L (as determined in an inhalation study with Sprague-Dawley rats).

Inhalation Risk From Handler Exposures

The calculations of inhalation risk indicate that MOEs are more than **300** at **baseline** for all the assessed scenarios with the exception of:

- (8) Applying liquids as a tree bark treatment using a paintbrush when applying 10 gallons in one 8 hour workday.

The scenarios which were assessed at baseline for inhalation risks, and which have MOEs greater than **300** include the following:

- (1a) Mixing/loading liquid formulations for aerial/chemigation application,
- (1b) Mixing/loading liquid formulations for groundboom application ,
- (1c) Mixing/loading liquid formulations for airblast sprayer application,
- (1d) Mixing/loading liquid formulations for application with a high-pressure handwand,
- (5) Applying sprays with a groundboom,
- (6) Applying sprays with an airblast,
- (7) Applying sprays with a high-pressure handwand,
- (8) Applying liquids as a tree bark treatment using a paintbrush when applying 5 gallons in one 8 hour workday,

- 9: (11) Applying sprays with a backpack sprayer,
- (12) Applying sprays with a low pressure handwand, and
- (13) Flagging aerial applications.

The calculations of inhalation risk indicate that MOEs are more than **300** with **PPE** for the following scenarios:

- (8) Applying liquids as a tree bark treatment using a paintbrush when applying 10 gallons in one 8-hour day.

The calculations of inhalation risk indicate that MOEs are more than **300** with **engineering controls** for the following scenarios:

- (2a) Mixing/loading water soluble bags (gel packs) for aerial/chemigation application,
- (2b) Mixing/loading water soluble bags (gel packs) for groundboom application,
- (2c) Mixing/loading water soluble bags (gel packs) for airblast sprayer,
- (2d) Mixing, loading water soluble bags (gel packs) for high-pressure handwand,
- (3) Applying sprays with fixed-wing aircraft, and
- (4) Applying sprays with a helicopter.

Aggregate Risk Indices for Handlers

Aggregate risk indices (ARIs) are used to combine dermal and inhalation MOEs when the uncertainty factors (i.e., acceptable MOEs) are dissimilar. For example, in this assessment the dermal uncertainty factor is 100, while the uncertainty factor for inhalation is 300. An ARI normalizes all uncertainty factors to one; therefore, an ARI of less than one is indicative of an unacceptable risk. ARIs are calculated using the following formula:

$$ARI = 1 / \{ [1 / (Dermal MOE / Dermal UF)] + [1 / (Inhalation MOE / Inhalation UF)] \}$$

Short-term ARIs

The calculations of total short-term risk indicate that the ARIs are more than **1** at **baseline** for all the following scenarios:

- (5) Applying sprays with a groundboom (high confidence in hand dermal data; no PFs used), and
- (13) Flagging aerial sprays (high confidence in all data; no PFs used).

The calculations of total short-term risk indicate that the ARIs are more than **1** with additional **PPE** for the following scenarios:

- (1a) Mixing/loading liquid formulations for aerial/chemigation application using an application rate of 0.375 lb ai/acre (e.g., walnuts),

- (1b) Mixing/loading liquid formulations for groundboom application (all application rates),
- (1c) Mixing/loading liquid formulations for airblast sprayer application (all application rates),
- (1d) Mixing/loading liquid formulations for application with a high-pressure handwand, and
- (6) Applying sprays with an airblast using an application rate of 0.375 lb ai/acre (e.g., grapes).

The calculations of total short-term risk indicate that the ARIs are more than 1 with **engineering controls** for the following scenarios:

- (1a) Mixing/loading liquid formulations for aerial/chemigation application using an application rate of 1.0 lb ai/acre and 0.75 lb ai/acre (e.g., safflower and cabbage),
- (2b) Mixing/loading water soluble bags (gel packs) for groundboom application,
- (2c) Mixing/loading water soluble bags (gel packs) for airblast sprayer,
- (2d) Mixing, loading water soluble bags (gel packs) for high-pressure handwand,
- (3) Applying sprays with fixed-wing aircraft,
- (4) Applying sprays with helicopter, and
- (6) Applying sprays with an airblast using an application rate of 1.125 lb ai/acre (e.g., tree crops).

Intermediate-term ARIs

The calculations of total intermediate-term risk indicate that ARIs are more than 1 at **baseline** for none of the scenarios.

The calculations of total intermediate-term risk indicate that ARIs are more than 1 with **additional PPE** for none of the scenarios.

The calculations of total intermediate-term risk indicate that ARIs are more than 1 with **engineering controls** for the following scenarios:

- (1c) Mixing/loading liquid formulations for airblast spraying (all application rates),
- (1d) Mixing/loading liquid formulations for application with a high-pressure handwand, and
- (13) Flagging aerial sprays.

Data Gaps in Both Dermal and Inhalation Assessment

There were no PHED data for the following scenarios, and therefore dermal and inhalation risks could not be assessed:

- (9) applications for tree injection (ready-to-use liquids), and
- (10) mixing/loading/applying liquids using soil injection.

Sections IV and V are deferred until decisions are made about the unacceptable risks for handlers and post-application workers.

References:

- 1) Metasystox-R label. EPA Reg. No. 10163-220, dated January 7, 1997.
- 2) EPA BEAD memo, 1995. Oxydemeton-Methyl Exposure Parameters for Selected Crops. Received by Versar on 8/2/95.
- 3) EPA OREB memo, 1993. Review of Acceptability of Worker Exposure Data Submitted to Support the Reregistration of Oxydemeton-Methyl (Metasystox-R). Dated July 22, 1993.
- 4) EPA HED memo, 1998. Oxydemeton-Methyl: Hazard Identification Report. CASRN: 301-12-2, PC Code: 058702, Caswell No. 455.
- 5) LUIS Table for Exposure Assessors, 1997. Case 0258 Oxydemeton-Methyl Chemical 058702 Report run on 6/3/97.
- 6) Metasystox-R label. EPA Reg. No. 10163-220, dated September 18, 1995. (Lists a treatment for lygus bugs on safflower that is not listed in the more recent 1997 label.)

cc: M. Begley, SRRD (7508W)
OREB Chemical file - ODM - 058702